



THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 7991

Serial No.: 09/757,688

Examiner: L.S. Channavajjala

Filed: January 11, 2001

Group Art Unit: 1615

Title: DROSPIRENONE FOR HORMONE REPLACEMENT THERAPY

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**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**TIMING AND FEES**

Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- within three months of the filing date of a national application other than a CPA under § 1.53(d);
- within three months of the actual filing date of the national phase of a PCT application; OR
- before the mailing of a first substantive office action (including after filing of an RCE).

Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

- a final rejection under 37 C.F.R. § 1.113;
- termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR
- a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

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a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

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termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P. § 609(B)(2); OR

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AND is filed on or before payment of the issue fee; AND is accompanied by:

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**STATEMENTS UNDER 37 C.F.R. 1.97(e)**

Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

**CITED MATERIALS**

Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.

Copies of the materials listed are attached (except for the foregoing).

**NON-ENGLISH LANGUAGE REFERENCES**

An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone  
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Translation of other relevant information on foreign search report

**OTHER INFORMATION**

None

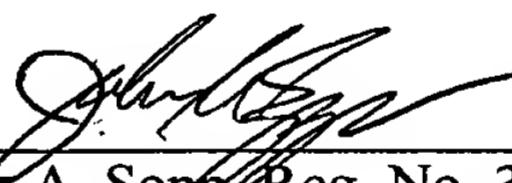
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Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

  
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Attorney for Applicants

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Attorney Docket No.: PLOVIN-2A

Date: December 10, 2003



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Substitute for form 1449A/PTO				Complete if Known	
				Application Number	09/757,688
				Filing Date	January 11, 2001
				First Named Inventor	Wolfgang HEIL et al.
				Group Art Unit	1615
				Examiner Name	L.S. Channavajjala
Sheet	1	of	5	Attorney Docket Number	PLOVIN-2A

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,569,652		Beier et al.	10-29-1996
	A4	5,583,129		Spona et al.	12-10-1996
	A5	5,824,667		Spona et al.	10-20-1998
	A6	5,827,843		Koninckx	10-27-1998
	A7	6,083,528		Elliesen et al.	07-04-2000
	A8	6,121,465		Mohr et al.	09-19-2000
	A9	6,346,269		Hsiao et al.	02-12-2002
	A10	RE37,564		Spona et al.	02-26-2002

FOREIGN PATENT DOCUMENTS						
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)		
	B1	DE	3022337	A1	Eiger et al.	01-07-1982
	B2	UK	2192542	A1	Upton	01-20-1988
	B3	WO	95/07081	A1	Koninckx	03-16-1995
	B4	WO	95/17194	A1	Spona et al.	06-29-1995
	B5	WO	95/26730	A1	Lachnit et al.	10-12-1995
	B6	WO	97/01342	A1	Schmidt-Gollwitzer	01-16-1997
	B7	WO	97/10827	A1	Petit et al.	03-27-1997
	B8	WO	98/27929	A2	Nashed	07-02-1998
	B9	WO	98/40069	A2	Klokkers et al.	09-17-1998

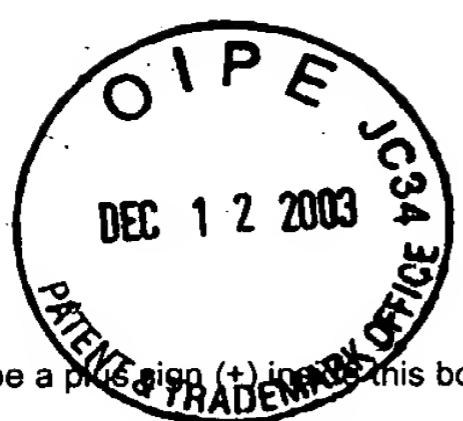
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	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565			
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<sup>1</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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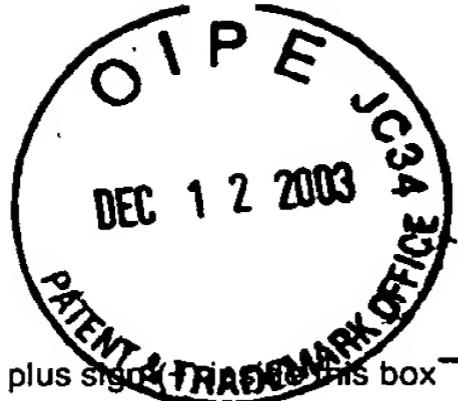
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	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992; 126 Suppl. 4, p. 71
	C3	Oelkers, "Effects of estrogens and progestogens on the renin-aldosterone system and blood pressure," <i>Steroids</i> , 1996 Apr.; 61(4): 166-71
	C4	Oelkers et al., (1991) "Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the Renin-Aldosterone System in Normal Women" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 73, No. 4, 837-842
	C5	Oelkers, "Effects of oral contraceptives on the renin – aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206
	C6	Kincl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84
	C7	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827
	C8	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626
	C9	Chakmakjian et al., "Bioavailability of Progesterone with Different Modes of Administration," <i>The Journal of Reproductive Medicine</i> , Vol. 32, No. 6, June 1987, pp. 443-448
	C10	Hargrove et al., "Absorption of oral progesterone is influenced by vehicle and particle size," <i>Am J Obstet Gynecol</i> , Vol. 161, No. 4, October 1989, pp. 948-951
	C11	Kohno et al., "Pharmacokinetics and Bioavailability of Diltiazem (CRD-401) in Dog," <i>Arzneim.-forsch./Drug Res.</i> , 27 (II), No. 7 (1977), pp. 1424-1428
	C12	Oelkers et al., (1995) "Effects of a New Oral Contraceptive Containing an Antimineralocorticoid Progestogen, Drosiprenone, on the Renin-Aldosterone System, Body Weight, Blood Pressure, Glucose Tolerance, and Lipid Metabolism" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 80, No. 6, 1816-1821
	C13	Nickisch et al., "Säure-katalysierte Umlagerungen von 15 $\beta$ ,16 $\beta$ -methylen-17 $\alpha$ -pregnen-27,17-carbolacton-derivaten," <i>Tetrahedron Letters</i> , Vol. 27, NO. 45, pp. 5463-5466, 1986 (and English translation)
	C14	Hartmann et al., "Comparison of galenic formulations of orlistat (tetrahydrolipstatin). A pharmacological approach," <i>Drug Investigation</i> , 1993, Vol/Iss/Pg. 5/1 (44-50)
	C15	Montel et al., "Development of a new tablet formulation of theophylline: in vivo studies," <i>Drug Development and Industrial Pharmacy</i> , 9(3), 399-420 (1983)

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Sheet

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	C16	Arias et al., "Dissolution properties and in vivo behaviour of triamterene in solid dispersions with polyethylene glycols," <i>Pharm-Acta-Helv</i> , (71, No. 4, 229-35 1996)	
	C17	Shah et al., "Preformulation study of etoposide: identification of physicochemical characteristics responsible for the low and erratic oral bioavailability of etoposide," <i>Pharm. Res.</i> 1989 May; 6 (5):408-12	
	C18	Berlin et al., "Phase I and pharmacokinetic study of a micronized formulation of carboxyamidotriazole, a calcium signal transduction inhibitor: toxicity, bioavailability and the effect of food," <i>Clinical Cancer Research</i> , 2002 Jan., Vol. 8 (1), 86-94	
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	C20	Duclos et al., "About a Pharmacokinetic Study of Progesterone in Comelts," <i>Eur-J-Drug-Metab-Pharmacokinet</i> , (15, No. 2, Suppl., Abstr. 226, 1990)	
	C21	Fell et al., "Bioavailability of griseofulvin from a novel capsule formulation," <i>The Journal of pharmacy and pharmacology</i> , 1978 Aug. Vol. 30 (8), p. 479-82	
	C22	Bruzzone et al., "Action of Gastric and Intestinal Simulated Juice on Meparticin Stability in Solid And Solubilized Form," <i>Il Farmaco - Ed. Pr.</i> , Vol. 32, No. 8, p. 422-428	
	C23	Andersson et al., "Pharmacokinetics and bioavailability of omeprazole after single and repeated oral administration in healthy subjects," <i>Br. J. clin. Pharmac.</i> , (1990), 29, 557-563	
	C24	Bozdag et al., "Formulation and stability evaluation of enteric-coated omeprazole formulations," <i>S.T.P. Pharma Sciences</i> 9 (4) 321-327 1999	
	C25	Nürnberg, "Manufacturing and Properties of Pharmaceutical Spray-Dried Products," <i>Acta Pharmaceutica Hungarica</i> 48. 19-35. 1978 (and English translation)	
	C26	Lehto et al., "The Effect of pH on the In-vitro Dissolution of Three Second-generation Sulphonylurea Preparations: Mechanism of Antacid-sulphonylurea Interaction," <i>J. Pharm. Pharmacol.</i> 1996, 48: 899-901	
	C27	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432	
	C28	"Bioavailability and Bioequivalence," <i>Biopharmacy</i> , Chapter 7 (English translation part 1/2 of page 202, Chapter 7)	
	C29	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C30	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20	

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## Group Art Unit

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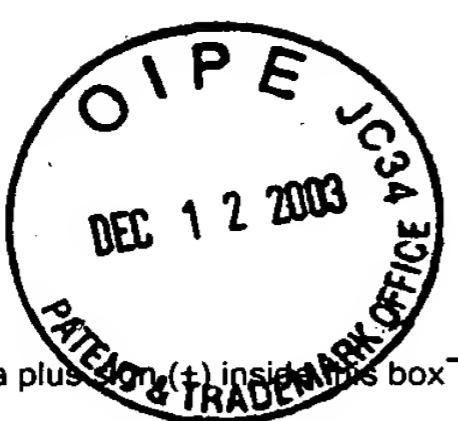
## NON-PATENT LITERATURE DOCUMENTS

NON PATENT LITERATURE DOCUMENTS		
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	<b>C31</b>	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256
	<b>C32</b>	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38
	<b>C33</b>	Fuhrmann et al., (1996) "The Novel Progestin Drospirenone and its Natural Counterpart Progesterone: Biochemical Profile and Antiandrogenic Potential" <i>Contraception</i> , 54: 243-251
	<b>C34</b>	Parsey et al., (2000) "An Open-Label, Multicenter Study to Evaluate Yasmin, a Low-Dose Combination Oral Contraceptive Containing Drospirenone, a New Progestogen" <i>Contraception</i> , 61: 105-111
	<b>C35</b>	Krause et al., "Isolation and Identification of Spirorenone Metabolites from the Monkey (Macaca Fascicularis)," <i>Steroids</i> , Vol. 40, No. 1, July 1982, pp. 81-90
	<b>C36</b>	Krause et al., "Determination of Plasma Levels of Spirorenone, a New Aldosterone Antagonist, and One of its Metabolites by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 230 (1982) 37-45
	<b>C37</b>	"Spirorenone," <i>Drugs of the Future</i> , Vol. 10, No. 6, 1985, pp. 479-481
	<b>C38</b>	Wilson et al., (1984). "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260
	<b>C39</b>	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)
	<b>C40</b>	Oelkers et al., (1974) "Effects of Progesterone and Four Synthetic Progestagens on Sodium balance and the Renin-Aldosterone System in Man" <i>J. Clin. Endocrinol Metab</i> 39, 882-890
	<b>C41</b>	Rylance et al., "Natural progesterone and antihypertensive action," <i>British Medical Journal</i> , Vol. 290, Jan. 5, 1985, p. 13-14
	<b>C42</b>	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 $\beta$ Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983
	<b>C43</b>	Mashchak, et al., "Estrogen Replacement Therapy and Hypertension," <i>The Journal of Reproductive Medicine</i> , Vol. 30, No. 10 (Supp)/October 1985, p. 805-810
	<b>C44</b>	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6
	<b>C45</b>	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p.987-993
	<b>C46</b>	Hayward et al., "Effect of Combination Hormone Replacement Therapy on Ambulatory Blood Pressure and Arterial Stiffness in Diabetic Postmenopausal Women," <i>American Journal of Hypertension</i> , July 2001, Vol. 14, No. 7, Part 1, pp. 699-703

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	C47	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142
	C48	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194
	C49	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
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